

## Response to Office Action

### A. *Status of the Claims*

Claims 33-47, 51, and 56-58 were pending. Claims 33 and 35 have been amended. Claim 58 has been canceled. Claims 33-47, 51, and 56-57 will be pending upon entry of the amendments.

### B. *Election*

Applicants confirm their earlier election of claim 51, without traverse, as noted in the final Office Action at page 3.

### C. *Withdrawal of Claim Rejections*

Applicants acknowledge and appreciate the Examiner's withdrawal of the Section 112 rejections lodged in the previous Office Action.

### D. *Section 103 Rejections*

Each pending claim stands rejected under 35 U.S.C. § 103 as being allegedly obvious in view of Eckenhoff and Biegajski. Applicants respectfully request the Examiner to reconsider and withdraw this rejection in view of the comments below.

#### 1. *The Amendments to the Claims Are Proper and Should Be Entered*

Claim 33 has been amended to recite a **bi-layer** wax-film composite comprising a pH-sensitive mucoadhesive layer **bonded to** a water-insoluble wax layer. This amendment does not raise any new issues that would require further consideration and/or search because (a) claim terms must be interpreted according to their definition in the specification, M.P.E.P. § 2111.01 and (b) the present specification already defines "wax-film composite" as being bi-layer with bonded layers. *See* specification, page 18. In other words, the amendment to claim 33 simply incorporates a definition that was already "built-into" the term "wax-film composite." Because no new issues are raised, the amendment to claim 33 is proper and should be entered. M.P.E.P. § 714.13.

Amended claim 33 also incorporates subject matter from now-canceled claim 58 (reciting that the composite has a total thickness of less than 5 mm). Because this material was already considered in dependent claim 58, no new issues are raised, and the amendment is proper.

The amendment to claim 35 is one of form and similarly raises no new issues that would prevent its entry.

The amendments to claims 33 and 35 place this application in condition for allowance or in better form for appeal. M.P.E.P. § 714.12. For this reason and those given above, Applicants respectfully request that the amendments be entered.

2. *The Claims Are Patentably Distinct from the Cited Art*

None of the cited art disclose, teach, or suggest a **bi-layer** wax-film composite comprising a pH-sensitive mucoadhesive layer **bonded to** a water-insoluble wax layer, where the composite has a total thickness of **less than 5 mm** as recited by amended claim 33. In particular, to the extent that the cited art could be argued to suggest a wax structure, it is not disclosed or suggested as being bi-layer wax-film composite with the particular layers of claim 33 bonded to one other. Further, the art does not disclose or suggest such a composite that also meets the thickness requirement (which can affect, among other things, adhesion time) now included in independent claim 33. For at least these reasons, Applicants respectfully request removal of the current obviousness rejection so that the claims can pass to issuance.

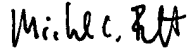
Applicants do not acquiesce to the Examiner's position outlined at pages 4-8 of the final Office Action. Applicants respectfully maintain that the original claims are allowable for at least the reasons provided in their previous response. Applicants have advanced the amendments and arguments here so that this case may pass swiftly to issuance and so that the original claims may be considered for inclusion in one or more continuing applications.

E. *Conclusion*

Applicants believe that this response fully addresses all outstanding matters. Applicants respectfully request that the rejections of all claims be withdrawn so the claims may swiftly pass to issuance.

Should the Examiner desire to sustain any of rejections, the courtesy of a telephone conference is respectfully requested in advance.

Respectfully submitted,



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